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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,349	12/19/2001	Yasuki Kato	5.1195	1803

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/018,349

Applicant(s)  
Kato

Examiner  
Gollamudi Kishore

Art Unit  
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

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### **DETAILED ACTION**

**The preliminary amendment and the priority document dated 19-12-01 are acknowledged.**

**Claims included in the prosecution are 1-25.**

#### ***Claim Rejections - 35 USC § 102***

**1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless -**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**2. Claims 1-6, 8, 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Law (4,933,121).**

**Law discloses a method of making liposomal compositions containing macromolecules such as proteins and enzymes. The liposomes are oligolamellar (more than two bilayers). The transition temperature of the phospholipids used is about 42 degrees; the sizes of the liposomes are 600 nm (above the temperature of the host). Note columns 2-3 and claims.**

**3. Claims 1-7, 10, 12-17, 19-21, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Woodle (5,356,633).**

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Woodle discloses a method of preparation of multilamellar vesicles (MLVs) containing a drug. The liposome sizes are 160 nm. The drugs include both steroidal and non-steroidal anti-inflammatory agents and anticancer agent, methotrexate. The lipids used for the preparation of MLVs are PEG-DSPE, DPPC, DSPC and cholesterol (note the abstract, Examples, Example 4 in particular and claims).

4. Claims 1-6, 10, 12-17, 19-20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Burke (5,552,156).

Burke discloses multilamellar vesicles containing the anti-cancer agents, camptothecins. The lipids include DSPC and cholesterol. Although Burke does not specifically state the sizes of MLVs, since the preparations are only vortexed and not sonicated, the sizes of more than 120 nm are implicit (note the abstract, col. 6, lines 11-46 and Examples 4-6).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-6, 9-10, 12-17, 19-20 and 22-23 are rejected under 35 U.S.C. 102 (a) or (b) as being anticipated by EP 0 850,646 of record.

EP discloses liposome formulations containing indolocarbazole derivatives. The liposomes are made from hydrogenated phospholipids, PEG-DSPE and cholesterol (note abstract, page 4, Examples and claims). Although, EP does not explicitly state that the liposomes are multilamellar, according the examples (example 1), the lipid film is hydrated

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and vortexed and not sonicated. Therefore, formation of multilamellar vesicles with sizes more than 120 nm is implicit.

The 102 (b) rejection will be reconsidered upon the review of the English translation of the Japanese priority.

*Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 7, 9-11 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Law (4,933,121 cited above).

As pointed out above, Law discloses a method of making liposomal compositions containing macromolecules such as proteins and enzymes. The liposomes are oligolamellar (more than two bilayers). The transition temperature of the phospholipids used is about 42 degrees; the sizes of the liposomes are 600 nm (above the temperature of the host).

Although Law does not specifically teach antibiotics and antitumor drugs, Law teaches that macromolecules can be encapsulated and exemplifies with proteins and enzymes.

Therefore, it would have been obvious to one of ordinary skill in the art that any desired drug could be encapsulated within the liposomes based on the guidance provided by Law.

Although Law exemplifies with 600 nm liposomes, one col. 3, line 30 suggests that one can

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regulate the sizes of the liposomes using extrusion to prepare liposomes of any sizes and therefore, preparing liposomes of sizes between 120 and 500 nm is deemed to be within the skill of the art.

8. Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Law (4,933,121) in view of EP cited above.

The teachings of Law relating to liposomes having encapsulated macromolecules and those of EP disclosing liposomal indolocarbazole derivatives have been discussed above. What is lacking in Law is the teaching of indolocarbazole derivatives as the macromolecule. However, it would have been obvious to one of ordinary skill in the art that any desired drug could be encapsulated within the liposomes based on the guidance provided by Law, especially in view of EP which teaches the knowledge in the art of encapsulation of this compound in the liposomes. One of ordinary skill in the art would expect similar encapsulation.

9. Claims 11 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Law (4,933,121) in view of (Mauer, BBA, 1998, 1374, pp., 9-20) of record.

The teachings of Law relating to liposomes having encapsulated macromolecules have been discussed above. What is lacking in Law is the teaching of antibiotics as the macromolecules. However, it would have been obvious to one of ordinary skill in the art that any desired drug could be encapsulated within the liposomes based on the guidance provided by Law, especially in view of the reference of Mauer which teaches

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the knowledge in the art of encapsulation of the antibiotic, ciprofloxacin in the liposomes (note the abstract). One of ordinary skill in the art would expect similar encapsulation.

10. Claims 8-9, 11, 18, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woodle cited above.

As pointed out above, Woodle discloses a method of preparation of multilamellar vesicles (MLVs) containing a drug. The liposome sizes are 160 nm. The drugs include both steroidal and non-steroidal anti-inflammatory agents and anticancer agent, methotrexate. The lipids used for the preparataion of MLVs are PEG-DSPE, DPPC, DSPC and cholesterol (note the abstract, Examples, Example 4 in particular and claims). Although Woodle does not teach the encapsulation of antibiotics or the claimed specific cancer drug it would have been obvious to one of ordinary skill in the art that any desired drug could be encapsulated within the liposomes based on the guidance provided by Woodle.

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**11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**



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**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**June 2, 2003**